AUG 1 6 2002

K021765

Tecres S.p.A. Cement Restrictor
Traditional 510(k)

510(k) Summary of Safety and Effectiveness

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Sponsor: Exactech® Inc.
2320 N.W. 66th Court
Gainesville, Florida 32653

Phone: (352) - 377 - 1140
Fax: (352) - 378 - 2617

FDA Establishment Numbers:

Applicant/Sponsor – Exactech # 1038671
Manufacturer – Tecres #1526534

Contact: Gary J. Miller, PH.D.
Executive Vice President of Research & Development
Exactech, Inc.

Date: May 24, 2002

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Classifications / Proprietary Names

Classification Name:	Prosthesis, Hip, Cement Restrictor
Product Code:	JDK
C.F.R. Section:	878.3300
Device Class:	II
Classification Panel:	General and Plastic Surgery
Common Name(s):	Cement Restrictor, Cement Plug
Trade / Proprietary Model Names:	Cement Restrictor – Small Cement Restrictor – Large

Legally Marketed Devices for Substantial Equivalence Comparison

The Tecres Cement Restrictor is substantially equivalent to the following legally marketed devices that were cleared for marketing via the premarket approval (510(k)) numbers listed below.

Manufacturer	Model	Product Code	510(k) Number
Tornier	Tornier Cement Restrictor	JDI	K001932
Sunmed, Inc.	Orthoplug Hard Bone Plug	LZN	K955631
Sunmed, Inc.	Orthoplug Soft Bone Plug	LZN	K955632
Zimmer, Inc.	Allen Medullary Cement Plugs, Zimmer Poly Plug Medullary Plugs	JDI	K001733
Osteonics Corp.	Omniflex-C UHMPE Mid-Shaft Restrictor	JDK	K923616

Device Description

The cement restrictor is a single, molded component intended to be used for blocking the diaphysis of the femoral canal. It is positioned a few centimeters distal to the distal tip of the prosthesis stem or the stem's centralizer to prevent migration of bone cement beyond the proximal zone of the femoral medullary canal. The cement restrictor is positioned with the aid of an insertion instrument.

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The restrictors are manufactured of radiolucent medical grade Ultra-High Molecular-Weight Polyethylene (UHMWPE) per ASTM standard F648-00, and ISO standards ISO 5834-1:1998 and ISO 5834-2:1998. They are manufactured in two sizes: "Small" and "Large." The small restrictors are to be used for femoral medullary canals ranging from 12 to 18 mm. The large restrictors are to be used for femoral medullary canals ranging from 18 to 24 mm.

One of each size restrictor is packaged in a bone cement preparation kit with other bone cement accessories, including:

- The cement restrictor inserter
- A femoral canal brush
- A femoral canal sponge
- A cement pressurizer, and
- Two curettes to aid in removal of excess bone cement.

The kit's packaging consists of a two-tray system with Copolyester (PETG) blister packs and Tyvek lids.

An alternative packaging is available in which a single restrictor is loaded onto its disposable, medical-grade Acrylonitrile Butadiene Styrene (ABS) insertion instrument. This assembly is packaged in double pouch system consisting of a laminate of polyethylene and polyamide. The final packaging for this version consists of a cardboard box.

Intended Use

The Tecres Cement Restrictor is inserted into the femoral medullary canal to limit the flow of bone cement and to aid in cement pressurization during primary or revision hip arthroplasty surgery.

Indications

Tecres Cement Restrictors are indicated for the blockage of the femoral medullary canal prior to cement insertion and as an aid to cemented hip arthroplasty procedures.

Contraindications

Tecres Cement Restrictors are contraindicated for non-cemented total hip procedures and for applications other than those which are indicated.

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Tecres Cement Restrictors are contraindicated in infectious arthritis and in active infection of the joint(s) to be replaced. Use of the cement restrictors is also contraindicated where the loss of musculature or neuromuscular compromise in the affected limb would render the surgical procedure unjustifiable.

The Tecres Cement Restrictors are NOT indicated for any spinal applications.

The Tecres Cement Restrictors are contraindicated for any patients exhibiting allergies to UHMWPE implant materials.

Sterilization

Tecres Cement Restrictors, whether in the kit or pouch packaging, are sterilized by gamma ray irradiation to a Sterility Assurance Level (SAL) of 10^{-6}.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 6 2002

Gary J. Miller, Ph.D.
Executive Vice President of Research and Deveopment
Exactech, Inc.
2320 NW 66th Court
Gainesville, Florida 32653

Re: K021765
Trade/Device Name: Tecres Cement Restrictors – Small and Large
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: JDK
Dated: May 24, 2002
Received: May 29, 2002

Dear Dr. Miller:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

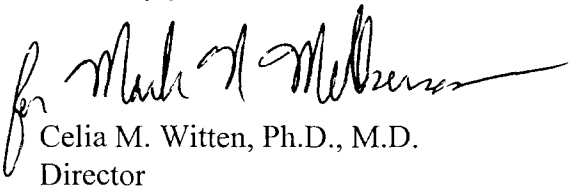
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html .

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Tecres S.p.A. Cement Restrictor
Traditional 510(k)

Indications for Use

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510(k) Number: K021765

Device Name: Cement Restrictors

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use K or Over the Counter Use _____

for Mark N Milham

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices
510(k) Number K021765 8/16/02